

serpentine configuration of alternating loops designed to allow radial self-expansion without any appreciable axial shortening.

In any event, the radially outward acting restoring force exerted by a given device when compressed to a certain radius less than its free-state radius, depends on the nature of the strands and the device geometry. More particularly, larger-diameter strands, a larger number of strands, and strands formed of a metal or other material having a higher modulus of elasticity, result in a higher level of restoring force. In structures employing helical strands, the restoring force can be increased by increasing the strand crossing angle, i.e. by winding the strands at a lower pitch angle.

Thus, radially self-expanding prostheses can be tailored to facilitate their fixation in a variety of different types and sizes of body lumens. At the same time, practitioners have encountered problems when using these prostheses in body lumens having natural curvature, such as the colon, the duodenum, the iliac and aortic arch, vena caval arch, brachial arch, and fallopian tubes. To illustrate the problem, Figure 1 schematically shows a curved vessel 1 with an occlusion 2. As seen in Figure 2, a stent 3 has been deployed within vessel 1 to maintain vessel patency, perhaps after an angioplasty balloon has been used to enlarge the vessel in the area of the occlusion. The radial force exerted by stent 3 is a key factor in maintaining vessel patency and in fixing the stent within the vessel.

Figure 2 reveals the tendency of stent 3 to straighten the naturally curved vessel, causing a kinking in the vessel (in this case, the colon) near the ends of the stent, as indicated at 4 and 5. The result is an unwanted narrowing of the vessel, and in the case of severe kinking, an obstruction. The source of this problem is the axial stiffness (lack of axial flexibility) of the stent.

The axial stiffness can be reduced by reducing the diameter of the strands making up the stent, using a strand material with a lower modulus of elasticity, or by reducing the number of strands involved. The trouble with these "solutions" is that each reduces the radially outward restoring force exerted by the stent when engaged with surrounding tissue as shown in Figure 2, with the result that the stent fails to provide the necessary degree of lumen patency and acute fixation.

their invention is one section of high axial force (which holds the lumen open) w/ one section that is flexible axially

In connection with prostheses formed of helically wound strands such as stent 3, axial flexibility can be improved by increasing the strand crossing angle of the helices. This approach may appear attractive at first, because the axial stiffness can be reduced without reducing the radially outward restoring force. As noted above, increasing the strand crossing angle increases the radially outward force. The difficulty lies in the fact that as the strand crossing angle increases, so does the extent of stent axial shortening occasioned by a given radial expansion. This increases the need for accurately matching the size of the intended stent with the lumen to be treated, given the increased penalty for excessive radial expansion of the stent once deployed. A related problem is the reduced tolerance for error in axially positioning the stent before its release from the catheter or other deployment device for radial self-expansion.

Therefore, it is an object of the present invention to provide a medical device deployable in a curved body lumen to maintain lumen patency, with axially extending segments of the device individually tailored to support either more gradually curved or more severely curved regions of the lumen.

Another object is to provide a process for fabricating a body insertable tubular structure with discrete axially extending segments in an arrangement of segments with a relatively high axial stiffness alternating with segments with a relatively high axial flexibility.

A further object of the invention is to provide a body insertable prosthesis which, when engaging surrounding tissue after its deployment, provides alternating regions varied selectively as to axial flexibility, radial stiffness, or both.

Yet another object is to provide a process for fabricating a body insertable prosthesis to selectively form discrete segments including at least one segment with relatively high radial force and axial stiffness, and at least one segment with a relatively low radial force and axial stiffness.

#### Summary of the Invention

To achieve these and other objects, there is provided a body insertable prosthesis. The prosthesis is a tubular structure including at least one flexible strand selectively formed to provide a plurality of discrete tubular segments including a first segment, a second segment spaced apart axially from the first segment, and a third segment disposed between the first and

